

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

IN RE: **C. R. BARD, INC.,**
 PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION

MDL No. 2187

THIS DOCUMENT RELATES TO CIVIL ACTION
NUMBER:

Jones v. C. R. Bard, Inc. 2:11-cv-00114

MEMORANDUM OPINION AND ORDER
**(Bard's Motion for Partial Summary Judgment Against Plaintiff and Plaintiff's Motion for
Summary Judgment on Bard's Affirmative Defenses)**

Pending before the court is Defendant C. R. Bard, Inc.'s ("Bard") Motion for Partial Summary Judgment Against Plaintiff Carolyn Jones [Docket 148] and Plaintiff's Motion for Partial Summary Judgment on Bard's Affirmative Defenses and Brief in Support Thereof [Docket 151]. Responses and replies have been filed, and the motions are ripe for review. As set forth below, Bard's motion for partial summary judgment is **GRANTED** in its entirety with respect to the manufacturing defect, failure to warn, breach of express warranty, breach of implied warranty, Mississippi consumer protection laws, and negligent inspection, marketing, packaging, and selling claims, and the plaintiff's motion for partial summary judgment is **GRANTED in part** as to Bard's contributory negligence affirmative defenses (Nos. 6, 12, and 14 in part) and federal preemption affirmative defense (No. 26) and **DENIED in part** as to the remaining defenses.

I. Background

This case is one of several thousand assigned to me by the Judicial Panel on Multidistrict Litigation and one of four bellwether cases currently set for trial pursuant to Pretrial Order # 32.¹ These MDLs involve use of transvaginal surgical mesh to treat pelvic organ prolapse or stress urinary incontinence. The four bellwether cases involve implantation of one or more products, but only the pelvic organ prolapse products are at issue. In this case, Carolyn Jones (the “plaintiff”) alleges that she suffered injuries as a result of the Avaulta Plus Biosynthetic Support System (“Avaulta product”) that was implanted in her. The Complaint alleges the following causes of action based on Ms. Jones’s injuries from the Avaulta product: 1) negligence; 2) strict liability – design defect; 3) strict liability – manufacturing defect; 4) strict liability – failure to warn; 5) breach of express warranty; 6) breach of implied warranty; 7) violation of Mississippi consumer protection laws; and 8) punitive damages. (*See* Compl. [Docket 1]). In the instant motions, Bard moves for summary judgment on several of these claims, and the plaintiff moves for summary judgment on several of Bard’s affirmative defenses.²

II. Legal Standards

A. *Summary Judgment*

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in

¹ Originally, there was a fifth case, *Smith v. C. R. Bard*, No. 2:10-cv-01355, which was terminated on February 22, 2013 pursuant to a Stipulation of Dismissal/Order.

² Pursuant to the court’s Pretrial Order # 72, *Daubert*-based dispositive motions, if any, pertaining to the other claims are to be filed at a later date.

the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587-88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict in his [or her] favor.” *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. See *Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm’ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), abrogated on other grounds, 490 U.S. 228 (1989).

B. *Choice of Law*

Under 28 U.S.C. § 1407, this court has authority to rule on pre-trial motions. In multidistrict litigation cases such as this, the choice-of-law for these pre-trial motions depends on whether they involve federal or state law. “When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.” *In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig.*, 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). In cases based on diversity jurisdiction, the choice-of-law rules

to be used are those of the states where the actions were originally filed. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) (“Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied.”); *In re Air Crash Disaster Near Chicago, Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010).

This case was originally filed in the Northern District of Mississippi. Therefore, I apply Mississippi choice-of-law rules. Mississippi applies the “most significant relationship” test as stated in the Restatement (Second) of Conflicts of Law. *McDaniel v. Ritter*, 556 So. 2d 303, 310 (Miss. 1989); *see also Boardman v. United Servs. Auto. Ass’n*, 470 So. 2d 1031-32 (Miss. 1985); *Mitchell v. Craft*, 211 So. 2d 509, 515 (Miss. 1968). The Restatement (Second) § 145 provides:

(1) The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in § 6.

(2) Contacts to be taken into account in applying the principles of § 6 to determine the law applicable to an issue include:

- (a) the place where the injury occurred,
- (b) the place where the conduct causing the injury occurred,
- (c) the domicile, residence, nationality, place of incorporation and place of business of the parties,
- (d) the place where the relationship, if any, between the parties is centered.

These contacts are to be evaluated according to their relative importance with respect to the particular issue.

Restatement (Second) of Conflicts of Laws § 145. Ms. Jones was and is a resident of the State of Mississippi, the surgery to implant Ms. Jones’s Avaulta product was performed in Mississippi,

and any alleged injuries occurred in Mississippi. Accordingly, Mississippi law applies to this case.

III. Bard's Motion for Summary Judgment

Bard argues that it is entitled to partial summary judgment because (1) the plaintiff's manufacturing defect claims fail for lack of evidence and (2) the plaintiff's failure to warn claims fail as a matter of law under the learned intermediary doctrine. Bard also moves for summary judgment on the plaintiff's claims under the theories of breach of warranty, Mississippi consumer protection laws, and negligent inspection, marketing, packaging, and selling.

I will address each of these issues below. However, I first note that the Mississippi Products Liability Act specifically codifies the four theories under which a plaintiff can bring a product liability suit:

1. The product was defective because it deviated in a material way from the manufacturer's specifications or from otherwise identical units manufactured to the same manufacturing specifications, or
2. The product was defective because it failed to contain adequate warnings or instructions, or
3. The product was designed in a defective manner, or
4. The product breached an express warranty or failed to conform to other express factual representations upon which the claimant justifiably relied in electing to use the product.

Miss. Code Ann. § 11-1-63(a)(i). In sum, the Mississippi statute specifically provides for the theories of (1) manufacturing defect; (2) failure to warn; (3) design defect; and (4) breach of express warranty.

A. *Manufacturing Defect*

Bard contends that the plaintiff has presented no evidence that the Avaulta product implanted in her deviated from the underlying specifications for Avaulta products generally, and

therefore the plaintiff has presented no evidence of a manufacturing defect under Mississippi law. The plaintiff contends that under Mississippi law, she can establish a manufacturing defect by producing evidence of inferior or defective materials, or evidence of a malfunction.

i. Law

The first issue for the court to resolve is the applicable law in Mississippi on manufacturing defect claims. As previously discussed, Mississippi law on manufacturing defects requires a showing that the product “deviated in a material way from the manufacturer’s specifications or from otherwise identical units manufactured to the same manufacturing specifications.” Miss. Code Ann. § 11-1-63(a)(i)(1). Relying on several cases stemming from *Cooper Tire & Rubber Co. v. Tuckier*, 826 So. 2d 679 (Miss. 2002), the plaintiff contends that under Mississippi law, she can make a claim for manufacturing defect under the “alternative methods” of showing “inferior or defective materials, or evidence of a malfunction.” (Pl.’s Resp. in Opp’n to Def. Bard’s Mot. for Partial Summ. J. [Docket 214], at 3) [hereinafter Pl.’s Resp.].

In *Cooper Tire*, a car accident occurred because one of the car’s tires had separated due to the defendant’s use of old rubber stock. The plaintiffs asserted that the use of “bad stock” in the manufacturing process led to the accident and subsequent death. *Cooper Tire*, 826 So. 2d at 681. The defendant contended that the plaintiffs never set forth the manufacturing specifications and made comparisons as necessary under Mississippi product liability law. *Id.* at 682. The court found that the plaintiffs met “their burden of proof when they put on expert testimony that the subject tire did in fact fail due to the use of bad stock.” *Id.* at 683. In doing so, the court simply accepted the “assertion that, even without the manufacturer’s specifications, the ‘good stock / bad stock’ distinction is an adequate standard against which a deviation may be established.” *Id.*

at 692 (Smith, J. dissenting).³ In other words, one way by which a plaintiff can show that a defective product deviated in some way from the standard design is by evidence of the use of inferior materials in that particular product. However, a plaintiff still must establish a deviation “from the manufacturer’s specifications or from otherwise identical units manufactured to the same manufacturing specifications.” Miss. Code Ann. § 11-1-63(a)(i)(1).

ii. Analysis

Viewing the facts in the light most favorable to the plaintiff, the plaintiff has produced evidence that: (1) the Avaulta products are exposed to thermal and mechanical stresses during the manufacturing process, which causes the products to degrade; (2) the manufacturer of the polypropylene material used in the Avaulta products warned Bard that the material can degrade during thermal processing; (3) the pore sizes of the Avaulta products are smaller than the pore sizes that Bard represented to doctors and to its sales personnel; and (4) Bard knowingly designed the Avaulta products using material which it knew was expressly prohibited by the manufacturer for human implantation.

While some of the above evidence relates to the manufacturing process of the Avaulta products, the plaintiff has provided no evidence that the Avaulta mesh that was ultimately implanted in her deviated from Bard’s “specifications or from otherwise identical units manufactured to the same manufacturing specifications.” Miss. Code Ann. § 11-1-63(a)(i)(1). For example, the plaintiff notes that one of her experts testified “that the heat set process employed by Bard in the manufacture of the Avaulta devices subjects the material to extreme temperatures ($290 \pm 15^\circ$ F), as well as mechanical forces during that heating process that

³ See also *Shelter Ins. Co. v. Mercedes Benz, USA*, No. 1:03CV592-M-D, 2006 WL 1601770, at *1-2 (N.D. Miss. June 8, 2006) (discussing *Cooper Tire* and holding that “[t]he plaintiffs were required to show that the defective car deviated in some way from the standard design—whether through active deviation from the manufacturer’s specifications or the use of inferior materials—and that the deviation resulted in the damages claimed”).

significantly exceed the mesh’s reported tensile strength.” (Pl.’s Resp. [Docket 214], at 5 n.4). Although this process is part of the manufacturing process of the Avaulta products, it would fall within the category of a *design* defect and not a *manufacturing* defect if the process, albeit faulty, were the same for all of these products. In contrast, if the expert had testified—for example—that the particular Avaulta product implanted in Ms. Jones went through thermal and mechanical processes that caused the product to degrade and which deviated from Bard’s processes for the same Avaulta products generally, then he may have provided evidence of a manufacturing defect.

Similarly, the alleged inadequate pore size and use of improper polypropylene material in the Avaulta products is a design issue—the plaintiff does not allege that the Avaulta product implanted in her had a different average pore size or was made out of different polypropylene material than Avaulta products generally. In sum, the plaintiff has provided no evidence that the Avaulta product implanted in her deviated in some way “from the manufacturer’s specifications or from otherwise identical units manufactured to the same manufacturing specifications.” Miss Code. Ann. § 11-1-63(a)(i)(1).⁴ Accordingly, Bard’s motion for summary judgment on the manufacturing defect claim is **GRANTED**.

B. *Failure to Warn*

Bard contends that it is entitled to summary judgment on the plaintiff’s failure to warn claim predicated upon strict liability and negligence because of Mississippi’s learned intermediary doctrine. As codified in the Mississippi Product Liability Act:

⁴ The plaintiff notes that Bard uses the term “manufacturing defect” when referring to Dr. El-Ghannam’s testimony on the thermal and mechanical processes used during the manufacture of the Avaulta products. (*See* Def. Bard’s Mem. of Law in Supp. of its Mot. to Exclude the Ops. & Testimony of Ahmed El-Ghannam, Ph.D. [Docket 143], at 15-18). However, it is clear that Dr. El-Ghannam’s opinion is that *all* Avaulta products go through this manufacturing process and therefore suffer from the same defect. (*See id.*). Accordingly, his opinions are related to design defects, notwithstanding any colloquial use of the term “manufacturing defect.”

An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe uses of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.

Miss. Code Ann. § 11-1-63(c)(ii); *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 691 (Miss. 1988) (citations and quotation marks omitted). The plaintiff does not contest that Bard was required only to warn her treating physician, Dr. David Williams, of the risks associated with the Avaulta product.

i. *Adequacy of the Warning*

Bard argues that the Avaulta product's instructions for use ("IFU") warned of the specific risks and complications that Ms. Jones complains of and that Dr. Williams was fully aware of the relevant risks. The plaintiff concedes that Bard provides a list of potential complications in the IFU, but argues that Bard "unquestionably failed to warn of numerous known risks associated with its products." (Pl.'s Resp. [Docket 214], at 11).

For example, the plaintiff provides evidence that Bard was in possession of a MSDS for the polypropylene resin used in the Avaulta product. The MSDS contained the following warning:

MEDICAL APPLICATION CAUTION: Do not use this Phillips Sumika Polypropylene Company material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.

(Material Safety Data Sheet [Docket 213-1]).⁵ The plaintiff produced evidence that Bard never provided this warning to Dr. Williams. Viewing the facts in the light most favorable to the plaintiff, she also provides evidence of other warnings that Bard never provided.

“An adequate warning is one reasonable under the circumstances.” *Wyeth*, 530 So. 2d at 692. “A warning may be held adequate as a matter of law where the adverse effect that was ultimately visited upon the patient was one that the manufacturer specifically warned against.” *Cather v. Catheter Tech. Corp.*, 753 F. Supp. 634, 640 (S.D. Miss. 1991) (applying Mississippi law). However, “[t]o be reasonable, the warning should neither understate nor overstate the known risks associated with the use of a particular product.” *Thomas v. Hoffman-LaRoche, Inc.*, 949 F.2d 806, 815 (5th Cir. 1992). Although Bard undisputedly warned of some potential adverse reactions in its IFU, I **FIND** that there is a genuine issue of material fact as to whether the warnings were adequate under the circumstances, given what Bard allegedly knew.

ii. *Whether the Inadequate Warning Proximately Caused the Alleged Injury*

Under Mississippi law, the failure to warn must have “proximately caused the damages for which recovery is sought.” Miss. Code Ann. § 11-1-63(a)(iii). In the context of a failure to warn claim, “even if the warning is inadequate, the burden is on the plaintiffs to show than [sic] an adequate warning would have altered” the treating physician’s conduct. *Janssen Pharmaceutica, Inc. v. Armond*, 866 So. 2d 1092, 1101 (Miss. 2004); *see also Wyeth*, 530 So. 2d at 691; *Thomas*, 949 F.2d at 817 (discussing whether an adequate warning would have changed the treating physician’s decision to prescribe the product). Bard argues that Dr. Williams never

⁵ Bard has not challenged the admissibility of the MSDS on any grounds in its summary judgment pleadings. The court is in receipt of a motion *in limine* as to the MSDS and will rule on that motion when it is ripe.

read the IFU and therefore, additional or different warnings would not have prevented him from implanting the Avaulta product into Ms. Jones. Dr. Williams testified:

Q. Did you – let me see if I can find – I show you what we'll mark as 3, and this is the Avaulta Plus, IFU they call it, Instructions For Use, that actually come with the Avaulta Plus product. You've gotten medical devices in the past, have you not, and they've got these instructions with them; is that correct? Just medical devices in general. They generally have a set of instructions with them, don't they?

A. In general, yes, sir.

Q. Do you recall the Avaulta Plus – this is the Avaulta Plus Biosynthetic Support System – do you recall ever having seen [the IFU] with the product? Glanced at it? Looked at it?

A. No.

(Williams Dep. [Docket 148-2], at 33:23-34:12). He also testified, regarding slings:

Q. And do you recall what those products – devices and what we call an IFU or information for use coming with those devices?

A. I never, you know, read that. I mean, the Cook, I probably did, but that's been 10 years. And the other was just I want to sample my product. Basically, the same mechanism or operative maneuvers. It was just a different sling. So I didn't feel like I had to read the fine print in the package insert.

(*Id.* at 94:13-94:21). Finally, he testified, with respect to the Avaulta product at issue in this case:

Q. Could you pass me that Exhibit right there on top. I'm referring to what's been as marked Exhibit 3 and this is what was introduced as the Instructions For Use for the Avaulta Plus. And I just want to make sure I'm clear. Do you recall ever reading the Instructions For Use for the Avaulta Plus product?

A. No.

(*Id.* at 95:4-95:11). The plaintiff offers testimony from Dr. Williams regarding information that he was not provided and that, had he known about such information, he would not have used the Avaulta product. (*See* Pl.'s Resp. [Docket 214], at 18-20). However, the plaintiff never directly

responds to Bard's argument that Dr. Williams simply never read the IFU. Dr. Williams's testimony essentially suggests that he felt he knew enough about the risks of implanting meshes such that he did not need to read the IFU. Accordingly, even drawing the facts and inferences in the light most favorable to the plaintiff, as the standard for a motion for summary judgment requires, I cannot find that the plaintiff has offered sufficient evidence to meet her burden of showing that additional or different warnings would have prevented Dr. Williams from implanting the Avaulta product into her. Simply put, because Dr. Williams did not review the IFU, no amount of warnings contained in it would have caused Dr. Williams to act any differently. *See, e.g., Latiolais v. Merck & Co.*, No. CV 06-02208 MRP (JTLx), 2007 WL 5861354, at *3-4 (C.D. Cal. Feb. 6, 2007);⁶ *see also Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999) (finding no evidence of causation where surgeon failed to read package insert or company literature but relied on "surgical literature, his own experience, and the experience of his colleagues in weighing the risks and benefits of surgery with the mesh"). Accordingly, I **FIND** that there is no genuine issue of material fact as to whether Dr. Williams would have altered his conduct if adequate warnings were given, and Bard's motion for summary judgment on the failure to warn claim is **GRANTED**.

⁶ *Latiolais* found that the plaintiff failed to show causation because "[t]he prescribing physician . . . conclusively stated under oath that the inserts played no role in his decision to prescribe [the drug] . . . and that he otherwise could not recall if he ever read the package insert, or warnings, regarding [the drug].” 2007 WL 5861354, at *3. Similar to the instant case, the plaintiff in *Latiolais* “tries, unsuccessfully, to circumvent the dispositive fact of [the physician’s] actual failure to read any product information or warning from [the manufacturer] with a hypothetical inquiry about a stronger . . . warning’s expected effect on [the physician]’s treatment of Decedent.” *Id.* at *4. Because the treating physician relied on his clinical experience, as Dr. Williams did here, any hypothetical warning “would likely have been included in the very materials” that the physician “specifically disavowed reading in prescribing” the product. *Id.*

C. *The Plaintiff's Remaining Claims*

For various reasons, Bard contends that the plaintiff's claims for (1) breach of express warranty; (2) breach of implied warranty; (3) violations of Mississippi consumer protection laws; and (4) negligent inspection, marketing, packaging, and selling all fail. The plaintiff failed to address these arguments in her response and have not offered any evidence to support these claims. Accordingly, Bard's motion for summary judgment on these claims is **GRANTED**.

IV. The Plaintiff's Motion for Summary Judgment

The plaintiff argues that she is entitled to partial summary judgment on Bard's affirmative defenses related to (1) contributory negligence; (2) comparative negligence; (3) assumption of risk; (4) mitigation of damages; and (5) federal preemption. I will address each of these issues below.

A. *Contributory Negligence*

Mississippi recognizes the rule of pure comparative negligence by statute. *See* Miss. Code Ann. § 11-7-15; *Burton by Bradford v. Barnett*, 615 So. 2d 580, 582 (Miss. 1993). Because Mississippi does not recognize the rule of contributory negligence, the plaintiff's motion for summary judgment as to affirmative defenses 6, 12, and 14 is **GRANTED** to the extent they relate to contributory negligence.⁷

B. *Comparative Negligence*

Mississippi's comparative negligence statute states:

In all actions hereafter brought for personal injuries, or where such injuries have resulted in death, or for injury to property, the fact that the person injured, or the owner of the property, or person having control over the property may have been guilty of contributory negligence shall not bar a recovery, but damages shall be

⁷ In its response, Bard admits that “[b]y statute, Mississippi is a pure comparative negligence state.” (Def. Bard’s Mem. of Law in Opp’n to Pl.’s Mot. for Partial Summ. J. on Def.’s Affirmative Defenses [Docket 215], at 8). Bard then proceeds to discuss comparative negligence, with no mention of contributory negligence.

diminished by the jury in proportion to the amount of negligence attributable to the person injured, or the owner of the property, or the person having control over the property.

Miss. Code Ann. § 11-7-15. Under Mississippi's statute, a plaintiff's recovery will be reduced by the percent of the plaintiff's own negligence, regardless of the percentage of fault. Mississippi additionally recognizes that “[i]n actions involving joint tort-feasors, the trier of fact shall determine the percentage of fault for each party alleged to be at fault without regard to whether the joint tort-feasor is immune from damages.” Miss. Code Ann. § 85-5-7(5). In other words, Mississippi allows proof of third parties that may be at fault, not just the parties in the case.

The plaintiff argues that “there is a dearth of evidence that would establish or even suggest that Ms. Jones acted negligent[ly] in any way. Furthermore, Bard has not pointed to evidence of conduct, which if believed by the jury, would constitute negligence on the part of any non-party.” (Pl.’s Mot. for Partial Summ. J. on Def. Bard’s Affirmative Defenses & Brief in Support Thereof [Docket 151], at 6) [hereinafter Pl.’s Mot.]. Bard has provided some evidence that Ms. Jones suffered from several multiple medical conditions and that her actions or inactions with respect to some of these conditions may have contributed to the cause of her injuries. Bard has provided further evidence that Ms. Jones’ treating physician, Dr. David Williams, may also have contributed to the cause of her injuries. Given the issues surrounding the discovery posture and Bard’s proffer of evidence on this issue, the court feels compelled to deny summary judgment on this issue at this time.⁸ However, the court will allow the plaintiff to raise this issue again at a later time if she deems it appropriate. Accordingly, the plaintiff’s motion for summary judgment on this issue is **DENIED**.

⁸ The deadline for both parties’ motions for summary judgment was the same; however, the discovery schedule in this case is such that several expert and fact witnesses had not been deposed at the time these motions were filed.

C. Assumption of Risk

Mississippi recognizes the assumption of risk defense by statute, which states:

In any action alleging that a product is defective . . . the manufacturer or seller shall not be liable if the claimant (i) had knowledge of a condition of the product that was inconsistent with his safety; (ii) appreciated the danger in the condition; and (iii) deliberately and voluntarily chose to expose himself to the danger in such a manner to register assent on the continuance of the dangerous condition.

Miss. Code Ann. § 11-1-63(d); *see also Green v. Allendale Planting Co.*, 954 So. 2d 1032, 1040-41 (Miss. 2007). The plaintiff argues that Bard cannot point to any evidence that she knew the product was defective, appreciated the dangerous condition, and voluntarily exposed herself to the danger in “a manner to register assent on the continuance of the dangerous condition.” (Pl.’s Mot. [Docket 151], at 7). The plaintiff further argues that “[i]n order to prevail on an assumption of risk defense, Bard must concede the defectiveness of its design, and then establish that these Plaintiffs knowingly and voluntarily assumed that risk.” (Pl.’s Reply in Supp. of its Mot. for Partial Summ. J. on Def.’s Affirmative Defenses [Docket 244], at 7) [hereinafter Pl.’s Reply].

Whether the Avaulta products are defective has not yet been determined.⁹ Bard is certainly entitled to rely on alternative arguments. In other words, if the court or jury found that the Avaulta product was not defective, the inquiry would end; however, if the court or jury found that the Avaulta product was defective, it would then proceed with the inquiry as to whether Ms. Jones understood and assumed the risk of having the defective Avaulta product implanted in her.

Bard presents evidence that Ms. Jones signed two consent forms to implant the Avaulta products. The plaintiff has cited no binding authority to support her argument that the consent forms would be inadmissible in this case. The plaintiff additionally argues that the consent form “has absolutely no bearing on any issue in this product liability action, and certainly does not

⁹ The deadline for *Daubert* based dispositive motions has not yet passed, and from several of Bard’s filings, it appears that Bard intends to challenge the issue of design defect at that time.

represent the sort of voluntary acceptance of risks of defects within the Avaulta product that would support such affirmative defense.” (Pl.’s Reply [Docket 244], at 6). Bard has provided some evidence that Ms. Jones was advised of the risks and consented to the implantation of the Avaulta products anyway. Accordingly, even if the court or jury found that the Avaulta product was, in fact, defective, there would be a genuine issue of material fact as to whether Ms. Jones knew and understood of the defects and nonetheless consented. “[A]t the summary judgment stage the judge’s function is not himself to weigh the evidence and determine the truth of the matter but to determine whether there is a genuine issue for trial.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). I **FIND** that there is a genuine issue of material fact as to whether, even assuming the Avaulta product is defective, Ms. Jones nonetheless assumed the risks, and her motion for summary judgment on the assumption of risk defense is **DENIED**.

D. *Mitigation of Damages*

Both parties agree Mississippi law establishes that a party has a duty to mitigate his or her damages through reasonable efforts. *See Flight Line, Inc. v. Tanksley*, 608 So. 2d 1149, 1162-63 (Miss. 1992) (“Without question, a person injured in tort is required to take reasonable steps to mitigate his damages, and this, at the very least, includes giving attention to doctor’s orders regarding his course of recovery.”). The plaintiff argues that “Bard can cite no evidence that [she] failed to take reasonably diligent steps to mitigate her damages upon sustaining injuries attributable to Bard’s defective product.” (Pl.’s Mot. [Docket 151], at 8). Bard has produced some evidence that Ms. Jones could have mitigated some damages by (1) getting a second opinion prior to additional surgery; (2) getting shots to treat her back pain; and (3) following up with a specialist instead of deciding to stop seeing the specialist. (*See* Def. Bard’s Mem. of Law in Opp’n to Pl.’s Mot. for Partial Summ. J. on Def.’s Affirmative Defenses [Docket 215], at 12-

13) [hereinafter Bard's Resp.]. Again, given the issues surrounding the discovery posture and Bard's proffer of evidence on this issue, the court feels compelled to deny summary judgment on this issue at this time. However, the court will allow the plaintiff to raise this issue again at a later time if they deem it appropriate. Accordingly, the plaintiff's motion for summary judgment on this issue is **DENIED**.

E. *Federal Preemption*

The plaintiff argues that her state law claims are not barred by federal preemption under Supreme Court law, and therefore she is entitled to summary judgment as to the affirmative defense of federal preemption. Bard appears to concede that the plaintiff's state law claims are not expressly preempted under *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), but argues that they are impliedly preempted under *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court stated:

[I]t is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.

531 U.S. at 352-53; *see also Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (holding that "a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist").

Accordingly, the state law claims themselves may not be *based on* fraud against the FDA, but evidence as to whether Bard failed to provide certain information to the FDA may nonetheless be relevant to the state law claims. *See In re Medtronic, Inc., Implantable*

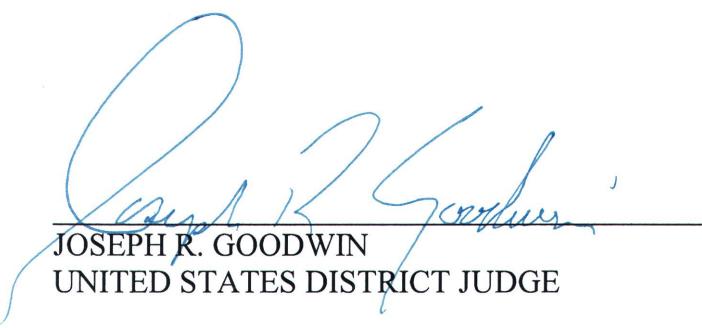
Defibrillators Litig., 465 F. Supp. 2d 886, 900 (D. Minn. 2006); *Bouchard v. Am. Home Prods. Corp.*, 213 F. Supp. 2d 802, 812 (N.D. Ohio 2002). Bard notes that its “interaction with the FDA is one of the points of contention in this case” and therefore “genuine issues of fact preclude summary judgment on this affirmative defense.” (Bard’s Resp. [Docket 215], at 17). The plaintiff argues that they “have not asserted, and do not intend to assert, any claim for ‘fraud on the FDA,’ whether ‘latent’ or otherwise.” (Pl.’s Reply [Docket 244], at 8). I agree that the plaintiff has not asserted any such claim. Accordingly, as a matter of law, the plaintiff is entitled to summary judgment on the issue of federal preemption, and her motion for summary judgment on this issue is **GRANTED**.

V. Conclusion

For the reasons discussed above, it is **ORDERED** that Bard’s motion for partial summary judgment [Docket 148] is **GRANTED** in its entirety with respect to the manufacturing defect, failure to warn, breach of express warranty, breach of implied warranty, Mississippi consumer protection laws, and negligent inspection, marketing, packaging, and selling claims. It is further **ORDERED** that the plaintiff’s motion for partial summary judgment [Docket 151] is **GRANTED in part** as to Bard’s contributory negligence affirmative defenses (Nos. 6, 12, and 14 in part) and federal preemption affirmative defense (No. 26) and **DENIED in part** as to the remaining defenses.

The Court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: June 4, 2013


JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE